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ELITe InGenius® SP 200
 Reagents for Nucleic Acid Extraction

REF INT032SP200

INTENDED USE

The product **ELITe InGenius® SP 200** extraction cartridge (catalog number INT032SP200) provides reagents used in association with the **ELITe InGenius®** instrument (catalog number INT030-K) to perform extractions and purification of nucleic acids. **ELITe InGenius** system, is a fully automated molecular diagnostics system performing extraction, purification, amplification and detection.

DESCRIPTION

The **ELITe InGenius SP 200** is a cartridge containing reagents for extraction and purification of nucleic acids (NA).

ELITe InGenius SP 200 (catalog number INT032SP200) is used on the **ELITe InGenius** (catalog number INT030-K) instrument and constitutes the **ELITe InGenius** System, when used along with fluorescence-based polymerase chain reaction reagents.

ELITe InGenius SP 200 may also be used on the **ELITe InGenius** instrument to perform extractions and purification of nucleic acids solely, without the NA being carried forward through the PCR amplification and detection stages.

The NA isolation protocol is based on magnetic beads and designed for the automated preparation of highly purified DNA (human, bacterial and viral) and viral RNA.

PRINCIPLES

The **ELITe InGenius SP 200** is the reagent set for automated NA extraction and purification from liquid biological samples on the **ELITe InGenius**. The reagent set has been optimized for the isolation of nucleic acids from 200 µL samples. The resulting nucleic acid eluate is then available for PCR with **ELITe InGenius**.

The NA isolation process is based on Magtration® Technology which utilizes magnetic beads for NA capture and a pipette tip and a magnet for liquid and bead manipulations.

The samples are lysed with a lysis solution in the presence of proteinase K and a nucleic acid carrier. Carrier RNA and an Internal Control template are added to the samples during the lysis step.

The released NA is adsorbed on the hydrophilic surface of magnetic beads leaving cellular debris and all extraction reagents in solution.

The unabsorbed materials are removed by magnetic bead separation followed by several washing steps. Finally, purified NA is eluted in distilled water, as shown in Figure A below.

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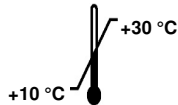


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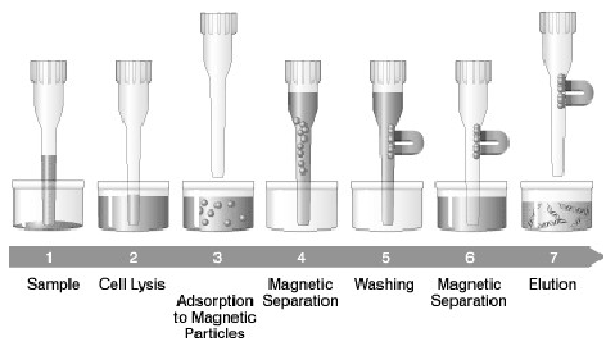


Figure A: Extraction Workflow

The purified nucleic acids are ready to use for downstream PCR experiments. Optionally, the purified nucleic acids may be stored at -20 °C or -70 °C for subsequent use.

NOTE: Each package provides reagents for **48 extractions** (e.g. 4 runs x 12 samples), where each extraction is performed by a single use cartridge, shown in Figure B.

MATERIALS PROVIDED

Each package contains 48 prefilled nucleic acid extraction cartridges, as shown in Figure B.

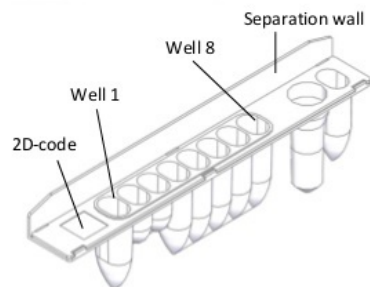


Figure B: Nucleic Acid Extraction Cartridge

Each nucleic acid extraction cartridge is configured as follows:

Well No.	Reagent Name	Quantity	Hazard Codes
1	Lysis solution	400 µL	H302, H315, H318, H319, H335, H400, H410
2	PK solution	80 µL	-
3	Carrier solution	80 µL	-
4	Magnetic beads	200 µL	-
5	Binding buffer	1000 µL	H225, H319, H335, H361, H370, H372, H373
6	Wash buffer 1	1200 µL	
7	Wash buffer 2	700 µL	
8	Distilled water	1200 µL	-
9	Empty	-	-
10	Empty	-	-

NOTE: The two empty wells are used during the extraction process for sample heat treatment.

Handling and Storage

Powder free glove in nitril or similar material must be worn when handling the **ELiTe InGenius SP 200**.

The **ELiTe InGenius SP 200** extraction cartridge should be stored at room temperature (+10 / +30 °C).

Refer to the product label for the expiration date. When stored properly, the **ELiTe InGenius SP 200** is stable until the expiration date on the product label.

Do not freeze. Keep the extraction cartridge away from high temperatures, humidity, and vibration.

Avoid exposure to UV light or direct sunlight.

Store the extraction cartridge with the aluminum foil side up.

Material Quality Controls

ELITechGroup S.p.A. (EGSpA) guarantees the performance characteristics of the **ELiTe InGenius SP 200** for applications as described in the instrument's operator manual.

In accordance with the EGSpA certified Quality Management System, the **ELiTe InGenius SP 200** has been tested against established acceptance criteria to ensure consistent product quality.

ELiTe InGenius® SP 200

Reagents for Nucleic Acid Extraction

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MATERIALS REQUIRED BUT NOT PROVIDED

The following equipment and reagents are not provided:

- Disposable powder free gloves in nitrile or similar material.

OTHER PRODUCTS REQUIRED

This product must be used in association with the **ELiTe InGenius** instrument (catalog number INT030-K) and with the **ELiTe InGenius SP 200 Consumables Set** (catalog number INT032CS).

WARNINGS AND PRECAUTIONS

This product is exclusively designed for *in-vitro* use.

Refer to the product label for more product information.

Warnings and precautions specific for the components

The components of the **ELiTe InGenius SP 200** listed below contain hazardous reagents. GHS Hazard and Precautions phrases applied to those components are listed below.

Do not reuse extraction cartridge or other consumables.

Allow to come to room temperature before use.

Do not freeze.

Do not damage or obscure the 2D code label.

When liquid drops are present on the wall of the cartridge well, shake gently without creating bubbles to move the drops down to the bottom of the tube.

Elution is performed with distilled water, and the final volume of eluate may be affected by residues on the magnetic beads, on the tip surface or by evaporation.

Please, note that hazard labeling is not necessary for quantities less than 125 g or 125 mL.

General warnings and precautions

Handle and dispose of all biological samples as if they were able to transmit infective agents. Avoid direct contact with biological samples. Avoid splashing or spraying. All materials that come into contact with the biological samples must be treated for at least 30 minutes with 3% sodium hypochlorite or autoclaved for one hour at 121 °C before disposal.

If using biological samples, handle and dispose of all reagents and materials used to carry out the experiment as if they were able to transmit infective agents. Avoid direct contact with the reagents. Avoid splashing or spraying. Waste must be handled and disposed of in compliance with adequate safety standards.

Inspect components for damage upon receipt. If damage has occurred, immediately contact ELiTechGroup Molecular Diagnostics Customer Support.

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For United States customer/technical support:

Telephone: 1.800.453.2725

E-mail: mdx@elitechgroup.com

Website: www.elitechgroup.com

In the case of liquid spillage, refer to "Warnings and precautions specific for the components" and to the appropriate Safety Data Sheets (SDS).

The chemicals and plastic parts are for laboratory use only; they must be stored in the laboratory and are not to be used for purposes other than intended.

Wear suitable protective clothes and gloves and protect eyes and face.

Discard contaminated gloves.

Never pipette solutions by mouth.

Do not eat, drink, smoke or apply cosmetic products in the work areas.

Carefully wash hands after handling samples and reagents.

Dispose of leftover reagents and waste in compliance with local regulations.

Carefully read all provided product instructions before running the experiment.

While running the experiment, follow the instructions provided with the product.

Do not use the product after the indicated expiry date.

Do not use damaged components.

Only use reagents provided in the product and those recommended by the manufacturer.

Warnings and precautions for molecular biology

Molecular biology procedures, such as nucleic acid extraction, amplification and detection, require qualified and trained staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or contamination of the samples by amplification products.

The samples must be exclusively used for this type of analysis. Samples must be handled in a Class II Biological Safety Cabinet. Pipettes used to handle samples must be exclusively used for this specific purpose. The pipettes must be of the positive displacement type or be used with aerosol filter tips. The tips used must be free of DNase, RNase, DNA and RNA.

Lysis Solution

Contains Hexadecyl trimethylammonium chloride and Guanidinium chloride

**Danger**

H302:	Harmful if swallowed.
H315:	Causes skin irritation.
H319:	Causes serious eye irritation.
H335:	May cause respiratory irritation.
H400:	Very toxic to aquatic life.
H410:	Very toxic to aquatic life with long lasting effects.

ELITe InGenius® SP 200**Reagents for Nucleic Acid Extraction**

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P261:	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P264:	Wash the hands thoroughly after handling.
P270:	Do not eat, drink or smoke when using this product.
P271:	Use only outdoors or in a well-ventilated area.
P273:	Avoid release to the environment.
P280:	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312:	IF SWALLOWED: Call a POISON CENTER or a doctor if you feel unwell.
P302+P352:	IF ON SKIN: Wash with plenty of water.
P304+P340:	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if able to. Continue rinsing.
P312:	Call a POISON CENTER or a doctor if you feel unwell.
P321:	Specific treatment.
P330:	Rinse mouth.
P332+P313:	If skin irritation occurs: get medical advice/attention.
P337+P313:	If eye irritation persists get medical advice/attention.
P362:	Take off contaminated clothing.
P391:	Collect spillage.
P403+P233:	Store in a well ventilated place. Keep container tightly closed.
P405:	Store locked up.
P501:	Dispose of contents/container according to national regulation.

Binding Buffer, Wash Buffer 1, and Wash Buffer 2

Contains 2-propanol

**Danger**

H225:	Highly flammable liquid and vapor.
H319:	Causes serious eye irritation.
H335:	May cause respiratory irritation.
H361:	Suspected of damaging fertility or the unborn child.
H370:	Causes damage to organs.
H372:	Causes damage to organs through prolonged or repeated exposure.
H373:	May cause damage to organs through prolonged or repeated exposure.
P201:	Obtain special instructions before use.
P202:	Do not handle until all safety precautions have been read and understood.
P210:	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233:	Keep container tightly closed.
P240:	Ground/bond container and receiving equipment.

ELITe InGenius® SP 200**Reagents for Nucleic Acid Extraction**

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P241:	Use explosion-proof electrical/ventilating/lighting equipment.
P242:	Use only non-sparking tools.
P243:	Take precautionary measures against static discharge.
P260:	Do not breathe dust/fumes/gas/mist/vapours/spray.
P261:	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P264:	Wash hands thoroughly after handling.
P270:	Do not eat, drink or smoke when using this product.
P271:	Use only outdoors or in a well-ventilated area.
P280:	Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353:	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+P340:	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P311:	If exposed or concerned: Call a POISON CENTER or a doctor.
P308+P313:	If exposed: Call a POISON CENTER or a doctor.
P312:	Call a POISON CENTER or a doctor if you feel unwell.
P314:	Get medical advice/attention if you feel unwell.
P321:	Specific treatment.
P337+P313:	If eye irritation persists: Get medical advice/ attention.
P370+P378:	In case of fire: use carbon dioxide, foam, dry chemical and water fog to extinguish.
P403+P233:	Store in a well-ventilated place. Keep container tightly closed.
P403+P235:	Store in a well ventilated place. Keep cool.
P405:	Store locked up.
P501:	Dispose of contents/container according to national regulation.

For further information, see Safety Data Sheets.

No other component of the **ELITe InGenius SP 200** contains hazardous reagents that require GHS Hazard and Precautionary Statements.**Warnings and precautions specific for ELITE InGenius System**This extraction cartridge is dedicated for use on the **ELITe InGenius** instrument. Carefully read the instrument operator's manual prior to usage.

In the case of an instrument error message, please refer to instrument Operator's Manual.

Discard used gloves and wash hands after use.

SAMPLES AND CONTROLS

For reproducible and high yields of extraction, appropriate sample collection, transport and storage is essential.

Different primary tubes are available to use with the **ELITe InGenius SP 200**.

Note: Samples should not contain clots or other solid materials. Mix the sample to ensure a homogenous resuspension before loading onto the instrument. Multiple freeze-thaw cycles should be avoided.

Cutaneous and mucocutaneous lesion specimens

Cutaneous and mucocutaneous lesion specimens must be collected using a swab and stored in UTM (or compatible) viral transport media according to laboratory guidelines and stored at 4°C (nominal) for a maximum of 7 days or at -20°C (nominal) for 8 months.

Cutaneous and mucocutaneous lesion samples do not require pre-treatment and may be directly extracted.

Plasma collected in EDTA

Plasma samples must be collected in EDTA according to laboratory guidelines and stored 4°C (nominal) for a maximum of four hours. The plasma samples can be stored at -20°C for a maximum of two days or at -70°C for long term storage.

Plasma samples do not require pre-treatment and may be directly extracted.

Serum collected in EDTA

Serum samples must be collected according to laboratory guidelines and stored 4°C (nominal) for a maximum of four hours. The serum samples can be stored at -20°C for a maximum of two days or at -70°C for long term storage.

Serum samples do not require pre-treatment and may be directly extracted.

Interfering substances

Plasma samples **must not contain heparin**, as it is a powerful inhibitor of DNA polymerase enzymes (such as thermostable DNA polymerases and reverse transcriptase and leads to invalid or incorrect results in downstream experiments performed on the extracted DNA and RNA.

Any inhibitory effect caused by drugs that may be contained in the starting sample must be taken into account during experiments subsequently performed on the extracted nucleic acids.

Extraction quality controls

Extraction quality controls may be used for training, proficiency testing and external QC of the System. External controls may be used.

As a negative specimen processing control, the laboratory can use a negative sample that has already been tested with the downstream experiment or carry out a simulated extraction using molecular biology grade water in place of the sample.

As a positive specimen processing Control, the Laboratory can use a positive sample that has already been tested with the downstream experiment or a certified reference material.

Other test materials as specified by the experimenter

Samples must be transferable by pipette; ensure there are no clots or other solid materials.

PROCEDURE

Read the ELITe InGenius operator manual carefully.

PREPARATION OF SAMPLES

NOTE: Samples must be transferable by pipette; ensure there are no clots or other solid materials. If primary tubes are used and completely filled, please mix the sample to ensure a homogenous solution is formed before loading onto the instrument.

Minimum volume of samples in primary tubes

The procedure of the **ELITe InGenius** is optimized for the isolation of DNA and RNA from 200 µL samples. However, depending on sample tube type, a minimum sample volume is needed to prevent pipetting errors. The minimum volumes of sample required are shown in the table below.

Tube Type	Minimum volume of sample
13x75 U-bottom tube: BD 3.0 mL - BD 4.0 mL Vacutainer, Sarstedt 5 mL tube	2.2 mL
13x100mm U-bottom tube: BD 6.0 mL Vacutainer	4.2 mL

NOTE: If the **ELITe InGenius System** detects a low sample volume, it skips the sample and makes a note in the Result Report.

Minimum volume of samples in the sonication tubes

All sample types may be directly loaded into the system using the sonication tube included in the **ELITe InGenius SP 200 Consumable Set** (catalog number INT032CS). The minimum volume required when using sonication tubes is 200 µL.

DESCRIPTION OF THE EXTRACTION PROCEDURE

Extraction with the **ELITe InGenius SP 200** is performed automatically by the **ELITe InGenius**. Refer to the **ELITe InGenius** operator's manual to set up an automated extraction.

PROCEDURE LIMITATIONS

ELITechGroup Molecular Diagnostics does not provide validation of performance characteristics of the product in experimental applications.

Do not use plasma samples collected in heparin with this product. Heparin inhibits DNA polymerase enzymes and leads to invalid or incorrect results in subsequent steps of the analysis performed on the extracted nucleic acids.

Any inhibition from drugs that may be present in the starting sample may be evaluated in the extraction product depending upon how the extraction product is used.


This product must be handled by personnel qualified and trained in the processing of potentially infectious biological samples and dangerous chemical preparations in order to prevent accidents with potentially serious consequences for the user or other persons.

TROUBLESHOOTING


Problem	Probable Cause	Comments and Suggestions
Low yield of extraction or NA purity	Sample status	Verify that the sample storage condition is appropriate as reported in the sample and controls section. Use only fresh sample or sample stored under appropriate conditions. Extraction yield can vary from fresh or previously frozen sample.
	Reagent status	Verify that the extraction reagent cartridge storage condition is appropriate. In case the extraction reagent has been refrigerated, allow reagents to come to room temperature prior use. Do not freeze the reagents and avoid storage locations subject to vibration.
	Solid items residues	Sample with solid residues may cause tip obstruction, and the mixing process may not function properly. The sample should be a clear solution for smooth handling by the 200 µL pipette. Do not use solids in samples to be extracted.
	Contamination	Clean all instrument parts well after use, including all surfaces by using 70 % ethanol.
	Issues with automation system	Refer to the error code displayed in the instrument operator's manual.
RNA is degraded	Sample concentration too high	If the sample concentration is excessive the RNase cannot be inactivated. Dilute sample before loading
	Elution storage	Tighten cap of elution tube as soon as possible, and keep samples at -20 °C.
	External RNAase contamination	After use, clean all parts on the instrument surface carefully by using RNase removal agents.

SYMBOLS

REF Catalog Number


 Temperature limits


LOT Batch code


 Use by (last day of month)

IVD *in vitro* diagnostic medical device


CE Fulfills requirements of the European Directive 98\79\EC for *in vitro* diagnostic medical device

 Contains sufficient for "N" analyses


 Do not reuse

 Consult instruction for use


CONT Contents


 Keep away from sunlight

 Manufacturer

 Health Hazard

 Danger

 Flammable

 Acute aquatic toxicity

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